

Application No.: 10/574,526
Filing Date: January 23, 2007

REMARKS

The Office Action states that a new oath or declaration in compliance with 37 CFR 1.67(a) needs to be filed that identifies the instant application by its application number and filing date, and the date the preliminary amendment was filed. However, the previous Final Office Action of February 10, 2009 states that the preliminary amendment was not entered. As such, Applicant submits that no new declaration is required.

Also, the Examiner has renumbered claims 89-105 as claims 133-149. Under the renumbering of claims, claims 1-132 are cancelled. Claim 133 is currently amended. Support for the amendment to claim 133 can be found, for example, in paragraphs [0011]–[0013] of the specification. Claim 135 is currently amended. Support for the amendment to claim 135 can be found, for example, in paragraph [0010] of the specification. Applicant notes that amended claim 135 refers to a product available under the trademark Santee Oxygen, but complies with 35 U.S.C. § 112, second paragraph because claim 135 depends from claim 133, which properly identifies and describes the product. MPEP 706.03(d). Claim 147 is currently amended. Support for the amendment to claim 147 can be found, for example, in paragraphs [0010]–[0014]. Thus, claims 133-149 are pending for examination.

Discussion of Rejections Under 35 U.S.C. § 112, First Paragraph – Enablement & Written Description

Claims 133-149 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner notes that previously presented claims 133-149 do not state that the oxygen is tetrameric. Nonetheless, the Examiner insists that the claims must still be limited to tetrameric oxygen. According to the Examiner, the specification and claims as originally filed indicated the oxygen was tetrameric oxygen. *Office Action* at page 3-4. Based on this assumption that the specification and originally filed claims only provide disclosure for tetrameric oxygen, the Examiner maintains rejection of the claims under the premise that tetrameric oxygen does not exist or at most is highly unstable. *Id.* at pages 4-5.

Similarly, the Examiner rejects claims 133-149 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner argues that

the specification does not provide description that conveys possession of the claimed methods using oxygen that is not tetrameric. *Id.* at page 5. To bolster this argument, the Examiner states that paragraph [0009] of the specification states that “The invention therefore provides methods, apparatuses and systems for delivering tetrameric oxygen to tissues.”

Applicant respectfully disagrees. The specification discloses compositions having a concentration of “free available oxygen” in the range of about 10-25% by volume without limiting the form of oxygen to tetrameric oxygen. Paragraph [0011] clearly describes free available oxygen that is not limited to tetrameric oxygen. By contrast, where the specification provides written description for embodiments that particularly involve tetrameric oxygen, the specification does so explicitly. For example, paragraph [0010] explicitly describes an embodiment relating to a composition containing “25% dissolved oxygen (tetrameric oxygen O4).” (emphasis added). Here, it is unambiguous that the specification describes embodiments in which oxygen is tetrameric by expressly indicating so in parenthesis. Because the specification provides written description of oxygen not necessarily tetrameric, Applicant requests withdrawal of the rejections as failing to comply with the enablement and written description requirements of 35 U.S.C. § 112.

Although the fact that the specification provides written description for free available oxygen not limited to tetrameric oxygen renders moot the rejections based on the assumption that tetrameric oxygen does not exist or at most is highly unstable, Applicant addresses the existence and stability of tetrameric oxygen as a theoretical issue solely to expedite prosecution. Applicant submits herewith the following article: Sherwood et al., Translational spectroscopy studies of the photodissociation dynamics of O4-, J. Chem. Phys. 150 (24), 22 December 1996 (“Sherwood”). Sherwood describes photodissociation of tetrameric oxygen and states that “O4- is stable with respect to dissociation into O2 + O2- by 0.59 eV.” See page 10803, last full paragraph. Sherwood also states that “O4- is generated by crossing a pulsed supersonic expansion of neat O2 with a 1-keV electron beam.” See page 10804, first full paragraph. Moreover, Sherwood indicates that a threshold amount of electron-volts is required to destroy tetrameric oxygen into O2 species by photodissociation or photodetachment. Applicant submits, solely to expedite prosecution, that Sherwood empirically demonstrates the existence and stability of tetrameric oxygen, thus resolving the theoretical question raised by the PTO.

The Examiner also rejects claims 133-149 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement because the specification is not enabling for a method of increasing oxygen levels in a tissue with a composition other than a gas. According to the Examiner, one of ordinary skill in the art would be required to do undue experimentation to formulate the “described aqueous solution of *tetrameric oxygen* into other formulations while retaining the purported amount of free available oxygen concentration by volume.” (emphasis added) *Office Action* at page 7. The Examiner bases the rejections under the here-disproven assumption that tetrameric oxygen does not exist or is too unstable. As discussed above in detail, the specification clearly does not limit oxygen to tetrameric oxygen, rendering the rejections of claims 133-134 and 138-145 moot. The rejection of amended Claims 135-137 and 147-149 are further rendered moot by the recitation, respectively, of Santee Oxygen or tetrameric oxygen in the claims.

Additionally, Sherwood indicates that tetrameric oxygen exists in stable form. As such, the rejection of claims 135-136 and 147-149 are rendered moot. Based on the foregoing, Applicant respectfully requests withdrawal of rejections of claims 133-149 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102(b) or 103

The Examiner has rejected claims 133 and 143-149 under 35 U.S.C. § 102(b) as allegedly anticipated by Muller or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Muller. According to the Examiner, Muller discloses that air is composed of about 21% by volume of oxygen. *Office Action* at page 9.

As a preliminary matter, Applicant notes that Muller is not shown to be “printed publication” prior art. A reference is proven to be a “printed publication” “upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.” MPEP 2128. Here, no indicia whatsoever shows that Muller was sufficiently disseminated or made available to the public to be a printed publication prior to the filing date of the present application. There is no evidence that Muller was indexed or published in any particular accessible format. Indeed, the only identifying characteristic of the document is

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appearance of the putative author's name and copyright at the bottom of the pages. This, however, is insufficient to indicate that the document is a "printed publication" available as prior art according to MPEP 2128. The putative author's name alone and copyright date do not satisfactorily show that it was disseminated or otherwise made available as required by MPEP 2128. As such, Applicant requests withdrawal of the rejection of claims 133 and 143-149 as anticipated or rendered obvious by Muller.

On a substantive basis, Muller does not anticipate claims 133 and 143-149 because Muller fails to disclose each and every limitation of the claims. A claim is anticipated only if each and every element of the claim is expressly or inherently found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131. Amended claim 133 and claims 134-146 dependent therefrom require an "aqueous composition" comprising between about 10% and about 25% free available oxygen by volume. By contrast, Muller does not disclose an aqueous composition, but instead describes air. Additionally, amended claim 147 and claims 148 and 149 dependent therefrom require a composition which comprises tetrameric oxygen in aqueous solution providing between about 10% and about 25% free available oxygen by volume. Again, Muller does not disclose an aqueous composition. Therefore, Muller does not anticipate claims 133 and 143-149. Applicant requests withdrawal of the rejection of claims under 35 U.S.C. § 102(b).

With regard to the rejection of claims 133 and 143-149 under 35 U.S.C. § 103(a) as obvious over Muller, it is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability..." *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicants need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish that the prior art reference must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Additionally, the Examiner must establish a reasonable expectation of success.

The Examiner has not established a *prima facie* case of obviousness because Muller does not teach or suggest all of the claim limitations. As explained above, Muller does not disclose an

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aqueous composition as required by the claims. Furthermore, Muller, a reference that merely mentions oxygen content of air, provides no reasonable expectation of success for arriving at the claimed methods of increasing oxygen levels in a tissue or treating a medical condition involving administration of aqueous compositions. Because the Examiner has not established a *prima facie* case of obviousness, Applicant requests withdrawal of the rejection of claims 133 and 143-149 under 35 U.S.C. § 103(a).

CONCLUSION

Applicant has endeavored to respond to each of the rejections in the outstanding Office Action. In light of the above arguments it is believed that the present application is in condition for allowance. If any questions remain that may be resolved over the telephone the Examiner is hereby invited to telephone the undersigned directly as the number below.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: April 2, 2010

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AMEND

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